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Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

EVERINE VAN HOUTEN,

Plaintiff,

vs.

USPlabs, LLC, a Texas corporation, and
GNC Holdings, Inc., a Pennsylvania
corporation,

Defendants.

) CIVIL NO. CV13-00635 LEK/KSC
)

) DEFENDANTS' CONCISE
) STATEMENT OF FACTS;
) DECLARATION OF KEVIN W.
) HERRING; EXHIBITS "1"- "3";
) CERTIFICATE OF SERVICE

DEFENDANTS' CONCISE STATEMENT OF FACTS

Per Local Rule 56.1 of the Rules of the United States District Court for The District of Hawaii, Defendant USPLabs, LLC, and GNC Holdings, Inc. (together, Defendants), by and through their attorneys Ashford & Wriston LLP, submits a concise statement of facts in support of their Motion for Summary Judgment.

Facts	Support
1. Plaintiff failed to identify any expert or disclose any report, and is now precluded from doing so at trial.	
A. Plaintiff's deadline to identify experts and expert opinions was March 23 rd , 2015.	Declaration of Kevin Herring. ("Herring Declaration") ¶ 3.
B. Plaintiff did not identify any experts or expert opinions by March 23 rd , 2015.	Herring Declaration ¶ 4.
C. Plaintiff is precluded from introducing such expert evidence in any motion or at a hearing or trial.	Fed. R. Civ. P. Rules 26(a)(2) and 37(c)(1).
D. Plaintiff has not filed a motion or otherwise requested an extension of the deadline to identify experts and disclose expert reports.	Herring Declaration ¶ 5.
E. Under the circumstances of this case, expert evidence is required.	<u>Bynum v. Magno</u> , 125 F. Supp. 2d 1249, 1261 (D. Haw. 2000) (causation must be shown through expert testimony when causation is linked to a medical conclusion).

Facts	Support
2. The Product is not toxic.	
A. The Product's ingredients are Caffeine, Aegeline, Bauhinia Extract, Higenamine HCl, Hemerocallis Fulva extract, Yohimbe extract, Maltodextrin, Silicon Dioxide.	<u>See Opinion of Hartmut Jaeschke, Ph.D. ATS</u> , attached as Exhibit 2 .
B. None of the Product's components are known liver toxins.	<u>See id.</u> ; <u>see also Exhibit 1</u> .
C. Aegeline is a component of the Bael tree's leaves and fruit.	<u>See Exhibit 2</u> .
D. Bael extracts have demonstrated health benefits.	<u>Id.</u>
E. Aegeline has undergone several preclinical toxicity experiments.	<u>Id.</u>
F. The preclinical studies showed no indication of adverse effects or liver toxicity.	<u>Id.</u>
G. The preclinical studies showed that Aegeline is safe even when exposure is 10-30 times greater than the dosage contained in the Product.	<u>Id.</u>
H. A limited human pilot study was conducted where volunteers were treated with 200 mg and up to 800mg of Aegeline; no adverse effect or liver toxicity was observed.	<u>Id.</u>

Facts	Support
I. To a reasonable degree of medical certainty, given the long-standing use of Bael tree leaves and fruit, and the preclinical studies, Aegeline is not liver toxic.	<u>Id.</u>
3. There is no epidemiological evidence to support general causation.	
A. The Centers for Disease Control's report, "Acute hepatitis and liver failure of unknown etiology in Hawaii – 2013: Report of a Cluster Investigation," regarding the possible role of consumption of OxyElite in the etiology of liver failure in a number of Hawaii residents (CDC Report), is based on a flawed and unscientific "investigation."	<u>See Opinion Noel S. Weiss M.D., Dr.PH</u> , attached as Exhibit 3 .
B. The "investigation" upon which the CDC Report is based was not designed or conducted in a way such that measurement errors or other distortions were minimized.	<u>Id.</u>
C. Cases were defined as not only having sustained acute hepatitis and liver failure, but as having previously consumed a weight loss or muscle building dietary supplement.	<u>Id.</u>

D. As a result of this design, it was not possible to contrast cases and controls regarding a history of use of such supplements, and thus it was not possible for this investigation to examine the potential role of a supplement (whether OxyElite or any other) as a factor in the development of acute hepatitis and liver failure.	<u>Id.</u>
E. The “investigation” presented in the CDC Report did not have the potential to elucidate etiologic factors, and concluded the cause of the purported cluster of liver damage in Hawaii was unknown.	<u>Id.</u>
4. The Product did not cause the specific injuries alleged.	
A. Plaintiff’s alleged injuries were not caused by Defendants’ Products.	<u>See Opinion of Robert G. Gish, M.D., attached as Exhibit 1.</u>
B. Plaintiff’s alleged injuries are the result of a pre-existing gallstone disease.	<u>Id.</u>
C. Plaintiff’s gallstone disease led to her undergoing surgical removal of her gallbladder in 2011.	<u>Id.</u>
D. Even after removal of the gallbladder, patients with gallstone disease, like Plaintiff, remain prone to bile duct stones.	<u>Id.</u>

E. Bile duct stones can block the bile duct, and cause symptoms of abdominal pain, nausea, and spikes in liver enzyme levels.	Id.
F. To a very high degree of medical certainty, given Plaintiff's gallbladder condition, proclivity toward bile duct stones, and rapid spikes in liver enzyme levels, the injuries alleged were a result of Plaintiff's gallstone disease.	Id.

DATED: Honolulu, Hawaii; April 22, 2015.

/s/ Kevin W. Herring
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Attorney for Defendants